

FORM PTO 1390 (REV. 5-99) US DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY DOCKET NUMBER 2001_0136A
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. §371		U.S. APPLICATION NO. (if known) 697762821 NEW
International Application No. PCT/NO99/00244	International Filing Date July 28, 1999	Priority Date Claimed August 14, 1998
Title of Invention AQUEOUS PRESERVATIVE		
Applicant(s) For DO/EO/US: Ingvar Selmer-Olsen; Leif Hjørnevik; and Freddy Johnsen		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. §371. 2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. §371. 3. <input checked="" type="checkbox"/> This express request to begin national examination procedures (35 U.S.C. §371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. §371(b) and PCT Articles 22 and 39(1). 4. <input checked="" type="checkbox"/> A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date. 5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. §371(c)(2)) (in English) <ol style="list-style-type: none"> a. <input type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau). b. <input checked="" type="checkbox"/> has been transmitted by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US) 6. <input type="checkbox"/> A translation of the International Application into English (35 U.S.C. §371(c)(2)). 7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. §371(c)(3)). <ol style="list-style-type: none"> a. <input type="checkbox"/> are transmitted herewith (required only if not transmitted by the International Bureau). b. <input type="checkbox"/> have been transmitted by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> A translation of the amendments to the claims under PCT Article 19. 9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. §371(c)(4)). (Unexecuted) 10. <input type="checkbox"/> A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. §371(c)(5)). 		
Items 11. to 14. below concern other document(s) or information included:		
<ol style="list-style-type: none"> 11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input checked="" type="checkbox"/> A FIRST preliminary amendment. <ol style="list-style-type: none"> <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment. 14. <input checked="" type="checkbox"/> Other items or information: (a) Figs. 1-2 (A4 paper); (b) PCT Request; (c) Forms PCT/IB/304 and 308; (d) International Search Report; (e) International Preliminary Examination Report; and (f) Published international application (WO 00/08929). 		

U.S. APPLICATION NO. (if known) 09/762821 NEW		INTERNATIONAL APPLICATION NO. PCT/NO99/00244	ATTORNEY'S DOCKET NO. 2001_0136A
15. <input checked="" type="checkbox"/> The following fees are submitted		CALCULATIONS	PTO USE ONLY
BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(5)):			
Neither international preliminary examination fee nor international search fee paid to USPTO and International Search Report not prepared by the EPO or JPO		\$1000.00	
International Search Report has been prepared by the EPO or JPO		\$ 860.00	
International preliminary examination fee not paid at USPTO but international search paid to USPTO		\$ 710.00	
International preliminary examination fee paid to USPTO but claims did not satisfy provisions of PCT Article 33(1)-(4)		\$ 690.00	
International preliminary examination fee paid at USPTO and all claims satisfied provisions of PCT Article 33(1)-(4)		\$ 100.00	
ENTER APPROPRIATE BASIC FEE AMOUNT =		\$1,000.00	
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).		\$	
Claims	Number Filed	Number Extra	Rate
Total Claims	8 - 20 =	0	X \$18.00
Independent Claims	1 - 3 =	0	X \$80.00
Multiple dependent claim(s) (if applicable)		+ \$270.00	\$
TOTAL OF ABOVE CALCULATIONS =		\$1,000.00	
<input type="checkbox"/> Small Entity Status is hereby asserted. Above fees are reduced by 1/2.		\$	
SUBTOTAL =		\$1,000.00	
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).		\$	
TOTAL NATIONAL FEE =		\$1,000.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property +		\$	
TOTAL FEES ENCLOSED =		\$1,000.00	
		Amount to be refunded	\$
		Amount to be charged	\$
<p>a. <input checked="" type="checkbox"/> A check in the amount of <u>\$1,000.00</u> to cover the above fees is enclosed. A duplicate copy of this form is enclosed.</p> <p>b. <input type="checkbox"/> Please charge my Deposit Account No. 23-0975 in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>23-0975</u>.</p>			
<p>NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.</p>			
19. CORRESPONDENCE ADDRESS		<p>By: <u>Michael R. Davis</u> Michael R. Davis, Registration No. 25,134</p> <p>WENDEROTH, LIND & PONACK, L.L.P. 2033 "K" Street, N.W., Suite 800 Washington, D.C. 20006 Phone:(202) 721-8200 Fax:(202) 721-8250</p> <p>February 13, 2001</p>	
 000513 PATENT TRADEMARK OFFICE		<p>THE COMMISSIONER IS AUTHORIZED TO CHARGE ANY DEFICIENCY IN THE FEES FOR THIS PAPER TO DEPOSIT ACCOUNT NO. 23-0975</p> <p>[CHECK NO.] <u>41970</u></p> <p>[2001_0136A]</p>	

Aqueous Preservative

The present invention relates aqueous formic acid containing preservative for grass and other agricultural crops, fish and fish products and meat products, having reduced corrosiveness and irritation to skin.

Preserving high moisture grass as silage in anaerobic conditions has been common practice for many years. A fast drop in pH is important to inhibit plant respiration, enzymatic protein breakdown and development of undesired bacteria. The only desired process is the lactic acid fermentation, which stabilises the silage at low pH. The initial drop in pH from approximately 6 to about 4.5 is commonly obtained by adding formic acid at a rate of 2-5 litres/ton grass. Formic acid is the most widespread acid silage preservative mainly due to its efficient acidification and antimicrobial effect, according to J.M. Wilkinson et al. (1966) "Silage in Europe. A survey of 33 countries", Chalcombe Publications Ltd., Lincoln UK, and McDonald et al. (1991) "The Biochemistry of Silage", second Ed., Chalcombe Publications, Lincoln UK. Field surveys have shown that formic acid based silage additives have been the most efficient additive for high moisture grass (Nordang, L.Ø. "Surforundersøkelsen 1989-90", Faginfo, Statens fagtjeneste for landbruket, 6, 1991 and ADAS 1995, "Effect of additives on DM on fermentation", Grass Farmer, 57, 11). However, 85% formic acid has a high level of corrosion on skin and metal (machinery).

The principles of silage preservation of meat- and fish offals are basically the same as for grass. However, even more stress is put on an efficient acidifier to reduce the pH. This is because offal of animal origin contains very little sugar to produce lactic acid, and the buffering capacity is high.

Mixtures of formic acid and formate salts and also other organic acids (propionic acid and acetic acid and their respective salts) have been developed to reduce the corrosiveness of the acid product. The most successful formulation in terms of efficient preservation and success in major markets has been ammonium tetraformate, comprising about 64% formic acid, about 6% ammonia and the balance being water (EP-411.827B1). The plain ammonia tetraformate (ATF) has been better than standard formic acid (85%) in terms of corrosion and burns to skin according to P. Westgaard, Journal Buskap og Avdraat, Vol. 37, pp 246-247, 1985. But it is still desired to reduce these negative properties of this efficient preservative. The corrosion on carbon steel has recently been overcome by addition of corrosion inhibitors such as cocobetaine or polyglycoside described in Norwegian Patent Application No. 974200. The skin corrosion is, however, still considered subject to improvements as ATF-type preservatives in this respect have to be labelled with "Corrosion" sign and the risk phrase "Causes burns".

The problem is to reduce the skin corrosion and at the same time maintain the same acidifying effect and good effect on silage fermentation quality. Just increasing the pH of the preservative might solve the problem of skin corrosion, however, it would produce new problems such as a less efficient preservative.

Known additives for reduction of metal corrosion have not been found to substantially reduce skin corrosion. Addition to preservatives of large amounts of lignosulphonates are claimed to reduce skin corrosion, but this will dilute the preservative and require use of relatively high amounts of preservative to obtain desired effect.

In the patent application WO 96/24247 there is stated that the aim is to obtain a preservative containing formic acid that has reduced corrosiveness on the skin, metal and machinery. A composition is made containing at least one ester of an unsubstituted or substituted benzoic acid with a C₁-C₉ alcohol or a mixture of such esters and another ester component of an unaromatic C₁-C₂₀ carboxylic acid with a C₁-C₉ alcohol. The preservative further contains at least one C₁-C₄ carboxylic acid. The preservative may contain 1.5-3 weight% of the ester mixture. This composition is stated to have excellent preservative effect. Data are however not given for corrosiveness with regard to metal or skin.

The main objective of the present invention was to arrive at an improved formic acid containing preservative being less corrosive and irritating to skin .

Another objective was to arrive at a preservative which could be classified as non-corrosive after a four hour skin exposure and thereby bring this type of preservatives from class "Corrosive to skin" (§3.2.5) to "Irritating to skin" (§3.2.6) as defined in Official Journal of the European Communities L 110A, Vol 36, May 4th, 1993 (Annex IV of Commission Directive 93/21EEC).

A further objective was to find a skin corrosion inhibitor which would be effective when applied in minor amounts and thereby avoid dilution or major change of the basic preservative.

In the search for a new solution to the skin corrosion problem related to preservatives it was first decided to concentrate on formic acid containing preservatives, primarily an ATF preservative. It was also essential to maintain the acidifying effect and good effect on silage fermentation quality. Accordingly, reduction of the acidity of the preservative was ruled out. Further checking on known metal anticorrosion agents revealed that their effect on the reduction on skin corrosion was only marginal. Both the corrosion inhibitor cocobetaine and the antioxidant ehtoxyquin were found to be insufficient with regard to reduction of skin corrosion. Thus the mode of action for inhibitors for metal corrosion seemed to be different from what was observed for skin corrosion. One inhibitor for steel corrosion which the inventors found useful to check further was glycerol which has been applied in some preservative in small amounts (0.5%). On skin, however, addition of glycerol to the ATF first seemed to have no effect, but when the amount added was substantially increased, it was surprisingly found that glycerol was able to bring ATF from class "Corrosive to skin" to class "Irritating to skin". The main reason for investigating the effect of glycerol was that it is approved as feed additive in the EU list of additives (E422). Glycerol is further a valuable nutrient for animals and a substitute for several metabolic pathways.

A comprehensive test program was then started to find the real effect of glycerol compared with other additives to preservatives. These tests proved that glycerol indeed gave a substantial reduction of skin corrosion of the preservative. The necessary amount for obtaining desired reduction in skin corrosion was found to depend on several factors such us the degree of neutralisation of the formic acid with ammonia. But already with addition of more than 0.5 weight% glycerol the skin corrosion started to go down. The upper limit for the glycerol content was found to be more a practical and economic limit in view of the fact that glycerol also is a nutrient. With regard to reduction of skin corrosion, however, it was found that for most cases 1.5 weight% would be sufficient.

Thus the preservative according to the invention contains ammonium tetraformate or any other combination of formic acid and ammonia and should contain 0.5-5 weight% glycerol.

Preferably the glycerol content in the preservative should be in the range 0.75-1.5 weight%.

The preservative may contain at least one metal corrosion inhibitor such as cocobetaine or alkyl glycoside. The preservative may also contain antioxidant.

The invention is further explained and elucidated in connection with the description of the figures and the examples.

Figure 1 shows the effect of glycerol in ATF on skin corrosion observed the first 24 hours after exposure.

Figure 2 shows the effect of glycerol in ATF on how the skin resolved 22 days after exposure. A borderline for the maximum skin effects allowed for a non-corrosive preservative is indicated by a dotted line.

Example 1

This example shows the effect of ATF preservatives with various additives on test animals (Rabbits) exposed for four hours to the preservative. The tests were performed in compliance with that described in Annex to Commission Directive 92/69/EEC, Method B4 and OECD Guidelines for Testing of Chemicals, Method 404 (Official Journal of the European Communities L 383A, Vol. 35, 29. Dec. 1992).

The animals were exposed to the samples on local areas of shaved skin for 4 hours. After that, skin reactions were recorded after 1 hour, 24 hours, 48 hours, 72 hours, 8 days, 15 days and 22 days. If there were severe burns to the skin with erosion and/or necrotic tissue, the animals were terminated very soon, and the degree of healing was not assessed. If the first animal showed severe signs of skin corrosion, further animals were not allowed to be exposed to the chemical. The animals who had milder reactions were kept until day 22. It is critical whether the test animals show a complete healing of the skin (regenerating skin with hair) or whether there are scars (permanent damage).

In order to present the skin reaction as a numerical parameter there were made a score for each observed effect. The mean value of the 3 (4) animals at an early stage (1-24 hours after exposure) was calculated for each sample. The degree of lasting skin damage was calculated from the readings at day 15-22 after exposure. If one animal out of three showed permanent damage (scar) at day 22 the product would be classified as corrosive. The lowest mean value (borderline) for a corrosive classification was therefore 1.7 (score 5 divided by 3 observations). The recorded results from the tests are shown in Table 1. In the two last columns the mean reaction scores are shown. Reactions and Reaction scores are defined below.

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Table 1

Sample	pH	Animal	Time after completation of 4 hour exposure								Reaction score	
			1h	24h	48h	72h	Day 8	Day 15	Day 22	Early 1-24h	Day 22	
ATF	2.67	36m 45m 46m	+	+	0	0	0	0	0	3.3	3.3	
			#	cb	cb	cb	pe	es,ns	ns@			
			#	ce	ce	ce	pe	es,ns	ns@,sc			
ATF + 0.2% coco-betaine	2.67	37m 47m 48m 61f	0	0	0	0	0	0	0	3.5	1.8	
			#	cb	cb	cb	cb,pe	sc3	0			
			#	ce	ce	ce	ce,pe	ns	0			
			ce	term.	term.	term.	term.	term.	term.			
ATF + 2% ethoxy-quin	2.67	40m 54m 55m	#	#	0	0	0	0	0	3.5	1.8	
			wh,#	cb	cb	cb	sc,cb,pe	sc2	0			
			wh,#	term.	term.	term.	term.	term.	term.			
ATF + 0.5% glycerol	2.65	142f 1522f 153f	#	#	#	#	es1	ns@	term.	1.5	3.6	
			wh,#	#	#	#	#	sc	ns@ 1			
			wh,#	#	#	#	#	sc	ns@ 1			
ATF + 1.2% glycerol	2.66	69f 100f 101f	cb3	cb3	nc3	nc3	nc3	nc3	0	1.8	0	
			#,wh	#,wh	#,wh	#,wh	sc,#	ns	0			
			0	0	0	0	0	0	0			

Definition of Reactions:

- 0 no sign
 wh blanching
 ns new skin revealed
 sc scabbing
 ph petechial haemorrhage
 at atonia
 term. rabbit was killed due to cb/cs
 cba blanched area showing signs of chemical burn
 cb chemical burn (no erosion)
 ce corrosion/chemical burn-and areas of site eroded
 ns@ new skin with scar tissue (larger than 0.5 cm²)
 ns@1 new skin with scar tissue in small local foci.
 pe peeling
 + blue coloration to test site
 fs fissuring
 # brown coloration to test site
 es eschar
 nc necrotic tissue

Number after code indicates number of affected areas of the site.

Reaction Score (mean):

A score is given for each observation based on the severity of the different reactions.

Early reactions (1-24 hours after exposure)

<u>Code</u>	<u>Reaction</u>	<u>Severity score</u>
0	no sign	0
wh	blanching	0.5
+	Blue coloration to test site	1.0
#	brown coloration	1.5
ph	petechial haemorrhage	1.5
cba	blanched area showing signs of chemical burn	3
cb	chemical burn (no erosion)	4
ce	corrosion/chemical burn-and areas of site eroded	5
term.	rabbit was killed due to severe corrosion	5

Healing reactions (day 22 after exposure)

<u>Code</u>	<u>Healing reaction</u>	<u>Severity score</u>
0/ns	intact skin and hair/new skin	0
sc	scabbing	2
es1	eschar, small local foci	3
ns@1	new skin with scar tissue in small local foci	3
es	eschar large area	5
ns@	new skin with scar tissue	5
term.	rabbit was killed due to lasting damage.	5

From Table 1 and the Figure 1 it can be seen that when at least 0.5 weight% of glycerol is added to the ATF preservative, the skin corrosion is substantially reduced. The addition of 0.5 weight% glycerol gave a significant reduction in the first skin reactions observed 1-24 hours after exposure. This amount of glycol was, however, too small to give a 100% protection of the dose site, and small local foci of scabbing and small local scars appeared on day 22.

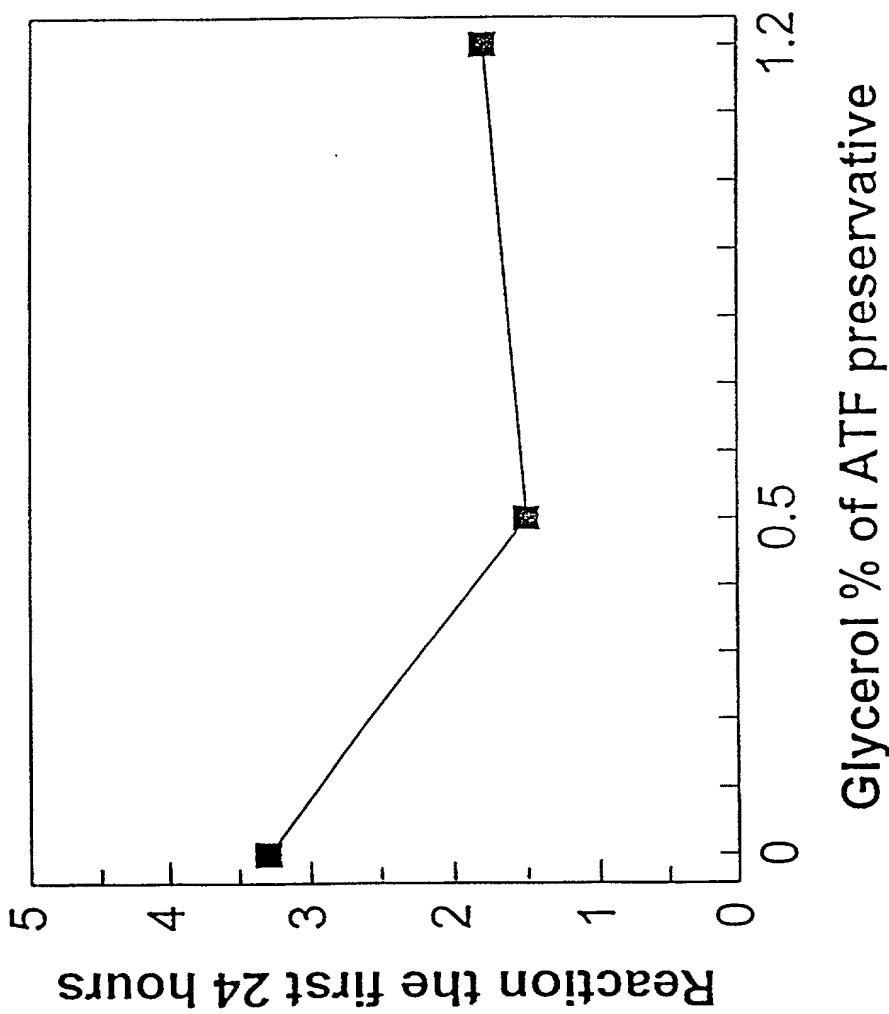
From Figure 2 it can be seen that a 1.2 weight% level of glycerol was enough to give full protection of the skin. Thus the new preservative can be classified as "Irritating to skin" contrary to the ATF without glycerol which is labelled "Corrosive to skin". It is further shown that when only 1.2 weight% glycerol is added, the severity score is well below that generally accepted (Borderline on Figure 2).

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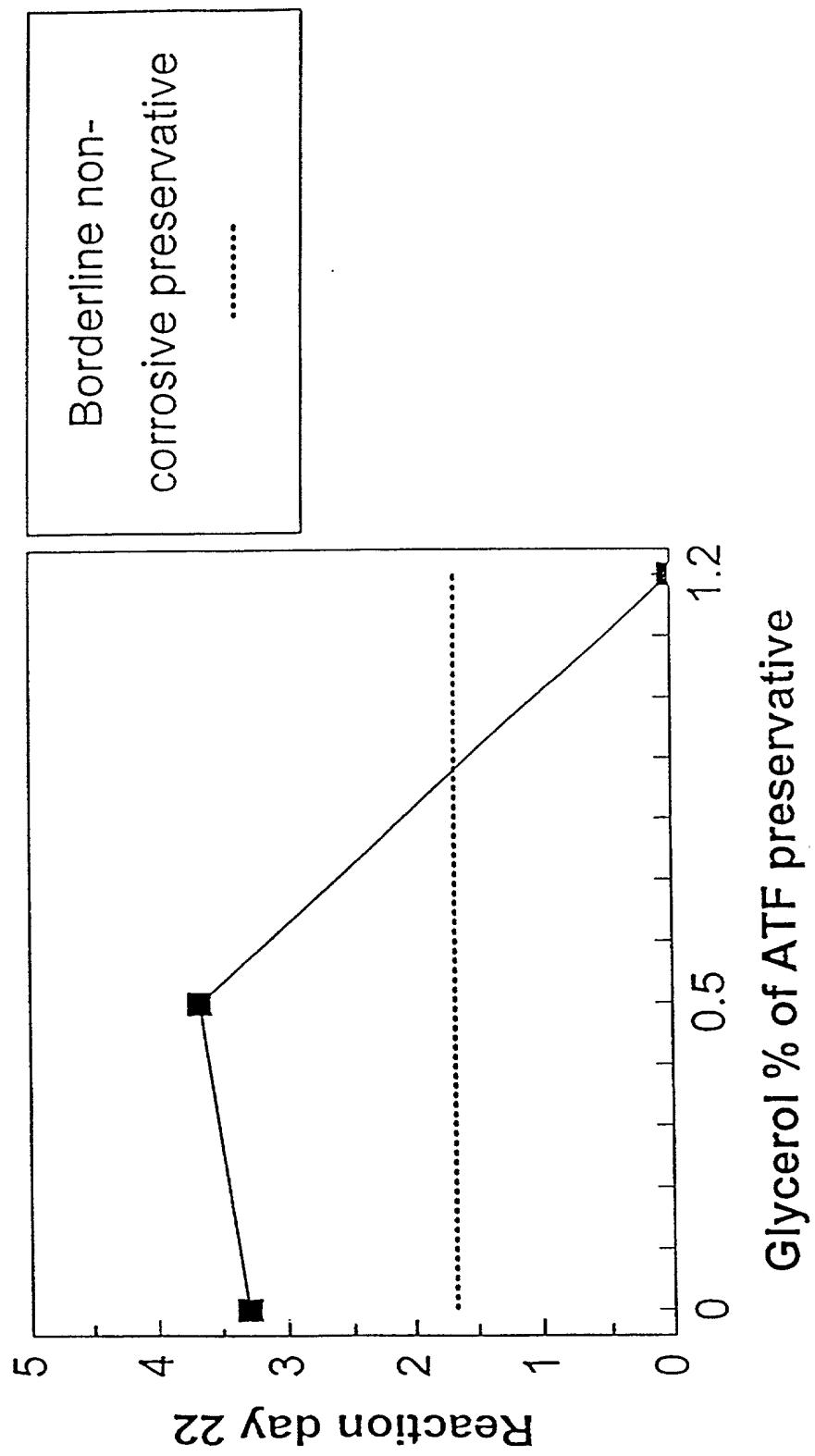
Claims

1. Aqueous preservative, containing ammonium tetraformate or any other combination of formic acid and ammonia, having reduced corrosiveness and irritation to skin, containing 0.5-5 weight% glycerol.
2. Preservative according to claim 1,
characterized in that
the preservative contains 0.75-1.5 weight% glycerol.
3. Preservative according to claim 1,
characterized in that
the preservative contains at least one metal corrosion inhibitor and/or antioxidant.
4. Preservative according to claim 1,
characterized in that
the preservative contains cocobetaine or alkyl glycoside as metal corrosion inhibitor.
5. Use of aqueous preservative according to claims 1-4,
for grass and other agricultural crops, fish and fish products and meat products.

1/2

Figure 1

2/2

Figure 2

DECLARATION AND POWER OF ATTORNEY FOR U.S. PATENT APPLICATION

(X) Original () Supplemental () Substitute () PCT () DESIGN

As a below named inventor, I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that I verily believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Title: AQUEOUS PRESERVATIVE

of which is described and claimed in:

- (the attached specification, or
 the specification in application Serial No. _____, filed February 13, 2001, and with amendments through February 13, 2001
 the specification in International Application No. PCT/NO99/00244, filed July 28, 1999, and as amended on August 12, 2000.

I hereby state that I have reviewed and understand the content of the above-identified specification, including the claims, as amended by any amendment(s) referred to above.

I acknowledge my duty to disclose to the Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I hereby claim priority benefits under Title 35, United States Code, §119 (and §172 if this application is for a Design) of any application(s) for patent or inventor's certificate listed below and have also identified below any application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

COUNTRY	APPLICATION NO.	DATE OF FILING	PRIORITY CLAIMED
Norway	19983729	August 14, 1998	YES

I hereby claim the benefit under Title 35, United States Code §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code §112, I acknowledge the duty to disclose information material to patentability as defined in Title 37, Code of Federal Regulations, §1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

APPLICATION SERIAL NO.	U.S. FILING DATE	STATUS: PATENTED, PENDING, ABANDONED

And I hereby appoint Michael R. Davis, Reg. No. 25,134; Matthew M. Jacob, Reg. No. 25,154; Warren M. Cheek, Jr., Reg. No. 33,367; Nils Pedersen, Reg. No. 33,145; Charles R. Watts, Reg. No. 33,142; and Michael S. Huppert, Reg. No. 40,268, who together constitute the firm of WENDEROTH, LIND & PONACK, L.L.P., as well as any other attorneys and agents associated with Customer No. 000513, to prosecute this application and to transact all business in the U.S. Patent and Trademark Office connected therewith.

I hereby authorize the U.S. attorneys and agents named herein to accept and follow instructions from NORSK HYDRO ASA as to any action to be taken in the U.S. Patent and Trademark Office regarding this application without direct communication between the U.S. attorneys and myself. In the event of a change in the persons from whom instructions may be taken, the U.S. attorneys named herein will be so notified by me.

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Residence & Citizenship	CITY	STATE OR COUNTRY	COUNTRY OF CITIZENSHIP
Post Office Address	ADDRESS	CITY	STATE OR COUNTRY ZIP CODE

I further declare that all statements made herein of my own knowledge are true, and that all statements on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

1st Inventor Ingvar Selmer-Olsen Ingvar
SELMER-OLSEN Date 26-02-2001

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HJØRNEVIK Date 22-02-

3rd Inventor Freddy Johnsen Freddy
JOHNSEN Date 12-03-

4th Inventor _____ Date _____

5th Inventor _____ Date _____

6th Inventor _____ Date _____

The above application may be more particularly identified as follows:

U.S. Application Serial No. 09/762,821 Filing Date February 13, 2001

Applicant Reference Number ASu:EMH-P9859 Atty Docket No. 2001_0136A

Title of Invention AQUEOUS PRESERVATIVE